Endoscope

with disposable cartridges for the invagination of endoscopic tube.

Description of invention.

BACKGROUND OF THE INVENTION.

1. Field of the Invention.

The invention relates to the field of medicine, namely to colonoscopy and enteroscopy, but can also be used for industrial endoscopes.

2. Description of Background Art.

Is known the device under U.S.Pat. 4,615,331 from Oct.7, 1986 to Kramann, comprising an endoscopic tube encased in an eversible elastic thin-walled tube which functions as a transporter-invaginator (hereinafter - invaginator) of the endoscopic tube. The invaginator in the device according to this patent is set in long layers parallel to the transported tube. One of the drawbacks of this device is the inconsistent unreeling of invaginator's layers, which is caused by their "sticking together" under air pressure and inevitable getting of air into spaces between them. Untimely evertion of any layer excludes from participation in intubation process the other layers, located above the everted one.

Is known also the intestinal endoscope under the inventor's certificate SU 1522466 from 0000-00-00 to Matasov with an invaginator set in pleats and placed at the right angle with an endoscopic tube transported by the invaginator. This endoscope is used as a basis to the present invention and has been taken as a closest prior art. The endoscope according to the closest prior art comprises: - a light source; - a source of excessive pressure; - an endoscopic tube with an eyepiece, a control block having a communication branch-tube and a stop for a spring; - an invaginator of endoscopic tube consisting of an uneverted part encased in an everted part, at that the uneverted part of invaginator tightly adjoins the endoscopic tube and is placed in pleats perpendicularly to it. From the side of the uneverted end the invaginator is supported by a spring and the area of transition of the uneverted part of the invaginator into the everted part is limited by a tip (in the meaning of the „tip cover") of the endoscopic tube. Furthermore, the endoscope according to the closest prior art comprises: - an external seal of the endoscopic tube to which the end of the everted part of the invaginator is fixed; - rings on the uneverted end of the invaginator; - an air-duct with a cock for feeding working pressure into the cavity of the everted part of the invaginator; - an anal dilator. Endoscopic tube of the closest prior art comprises light and image transmission elements, biopsy channels, channels for gas or liquid supply, and, in addition, comprises two pairs of close-coiled springs with traction lines which are pair-wise connected to the distal ring of a mechanism for bending a distal end of the endoscopic tube and rollers located in the control block and designed for manual extraction of traction lines.

The first drawback of the endoscope according to the closest prior art is unreliable operation of its invaginator resulting in difficulties with introduction of the endoscopic tube into the external seal (see lines 42-53 of the SU 1522466). The invaginator is to be everted under the tip, but during invagination the distal part of the endoscopic tube becomes bared. It can happen because of absence of a gap between the endoscopic tube and the uneverted part of the invaginator and because of a flabby structure of the latter, which cause the invaginator to adhere to the endoscopic tube under the air pressure. Tube pleats formed while bending the

distal end also prevent free movement of the invaginator along the endoscopic tube. As a result, the spring is unable to displace the invaginator toward the tip. In addition, the uneverted end of the invaginator, connected with two rings, does not ensure sufficient pressurization of the cavity of the everted part of the invaginator.

The second drawback of known endoscopes is that it is not possible to bend its distal end after the number of turns of an endoscopic tube has exceeded certain specific value. Its end is bent by rotation of two rollers each connected to its pair of traction lines. These traction lines are enclosed in springs, and the distal ends of springs are extended by channels in the wall of cardan-joined rings. Ends of traction lines are soldered to the distal ring of the cardan mechanism for bending of the distal end of the tube. Pulling a traction line out of a spring decreases gaps between cardan rings and forms a small radius of a turn. At that, the distal cardan ring pulls the opposite traction line in distal direction, thereby increasing the gaps between rings. Difference of lengths of big and small half-circumferences of the tube's turn is a product of "π" and diameter of an endoscopic tube. Japanese authors point out that when 3-4 loops are formed, the distal end of an endoscope is blocked, while biopsy forceps continue to function. This difference is explained by L. Aler formula

$$\frac{Q_1}{Q_2} = e^{a \cdot f},$$

where: "Q_1" - manual force extracting the traction line; "Q_2" - remaining from "Q_1" force applied to a distal cardan ring or to the cutters of biopsy forceps; "e" - basis of natural logarithm; "α" - traction line rotations in radians; "f" - friction index between a traction line and a spring. Under fixed values "Q_1" and "f", value "Q_2" depends on value "α", notice that for a pair of consecutively joined traction lines of an endoscope the value "α" is twice as large as for one traction line of biopsy forceps.

The third drawback of the prior art is the problem of its maintenance. For recurrent use, an endoscope needs to be washed, disinfected and sterilized. However, there are reported cases of infecting patients with AIDS and other diseases after endoscopy. Preparation of the endoscope according to the closest prior art for work requires its assembly. There are 10 detachable parts needed to be assembled in the endoscope according to the closest prior art, and its assembly takes about half an hour. Ergonomics of operating the existing endoscopes also complicates its mastering. Thus, the left hand holds the control block, switches on and off its cocks, rotates handles, which bend and fix the distal end of the tube, while the right hand introduces the tube into the intestine.

It has been proven in practice, that if endoscope makes more than 3-4 loops, then it is impossible to introduce biopsy forceps into it and to take a bioptate. This is the fourth drawback of the prior art.

SUMMARY OF THE INVENTION.

The objectives of the invention have been: - to increase reliability of invagination of an endoscopic tube; - to ensure bending of its distal end in flexuous channels; - to make maintenance of an endoscope more convenient; - to perform biopsy in flexuous channels. Implementation of said objectives will make colonoscopy available to any physician and will make it easier for experienced endoscopists.

These objectives have been achieved by the fact that the construction of an endoscope consisting of: - a source of light; - a source of pressure; - biopsy forceps; - an endoscopic tube with the control block and communication branch, at that the endoscopic tube comprises internally elements for light and image transmission, a channel gas/liquid, a biopsy channel, two pairs of springs with traction lines, which pair-wise connect the mechanism for bending the distal end of the endoscopic tube with manual extractors of traction lines located in the control block, and externally - a compressed spring placed on tubes distal end, an invaginator, a tip, a mobile seal, an anal dilator, has been further supplemented with:

- a disposable cartridge for the invagination of an endoscopic tube;
- a system of extractors-intractors of traction lines;
- an essentially changed endoscopic tube;
- a system of introduction and extraction of biopsy forceps;
- an intensifier of traction line of biopsy forceps.

The safety of introduction into the intestine and convenience of exploitation of the suggested endoscope is in the first turn ensured by the disposable sterile cartridge which consists of: - a shell with a projection at its proximal end, wherein are comprised: a preservative of the distal part of the endoscopic tube, which preservative is united with a spring stop on its proximal end; a compressed spring; a spring distancer wherein the distal seal of the endoscopic tube is located, which seal is fastened to an uneverted end of invaginator; a fixator of said compressed spring; an invaginator in the form of a compact hollow flexible cylinder, which has a gap with said preservative and recurrent narrowings of its external diameter and widenings of its internal diameter, at the same time the everted end of the invaginator is fastened on the distal end of the shell; - a proximal seal of the endoscopic tube, which seal is joined with the shell; - an anal dilator with a channel in its wall; - a tip of endoscopic tube united with the distal end of said preservative, which tip has a protective glass, a channel for washing of glass and for inflating of intestines, elements for hermetic joining to the endoscopic tube. The compact hollow flexible cylinder of the invaginator is formed of crumpled and tightly compressed in longitudinal and transverse directions variform pleats of an eversible thin-walled tube, placed at different angles with the longitudinal axis of the endoscopic tube. Moreover, the cartridge for invagination of the endoscopic tube is joined with a mechanism for introduction of said tube, which mechanism is made in the manner of a cylinder with two pistons, which are interconnected by distancers and an elastic tube, and the cavity between them communicates with a source of gas pressure through a pedal cock, at that the cavity between the proximal seal of the endoscopic tube and the distal piston encloses a spring, which returns pistons to their home position and through the pedal cock communicates with a source of vacuum.

The system of extractors-intractors of traction lines has a pneumo-hydro-manual drive and creates additional force equal to a few grams at the distal end of the traction lines. The system comprises sources of excess pressure and vacuum connected to cavities of elastic tubes, which cavities contain liquid and springs with traction lines, at that said tubes are fixed to said springs with a thread, the springs are made with spacings and are finished on some distance from an executing mechanism for bending the distal end, at that said traction lines on the distal end are connected with springs, and in the control block the traction lines are attached to manual extractors-intractors of traction lines united with elements which

ensure synchronous feeding of vacuum into the cavity of manually extracted traction line and feeding of excess pressure into the cavity of an introduced traction line. In order to create the additional force the distal end of the tube and of the traction line is possible to finish by a cylinder and a piston accordingly, or it is possible to finish the tube by an elastic element, for example, a sylphone, and the traction line to connect with sylphone's distal end. Manual extractors-intractors of the traction lines could be made in a manner of a rod, and the sources of pressure and vacuum – in a manner of a piston and a cylinder, positioned on the rod. An element, which ensures synchronous feeding of vacuum into the cavity of the extracted traction line and pressure into the cavity of the introduced traction line, could be a gear mated with cogs of two rods. As each of two gears is coupled only with its pair of traction lines, the bending of the tube's end is performed in two stages. The crosspiece with an operating lever, where the central part of the crosspiece is movably connected with the body of the control block, and the ends of the crosspiece are attached to four rods, ensures simultaneous bending of the tube's end in any direction.

A novel endoscopic tube is supplemented with: - an internal transverse pleats of its external cover; - two air-ducts, where the larger one has a lateral opening into the cavity of the proximal seal of the cartridge for invagination, and the smaller one - into the cavity of distal and proximal preservatives; - areas for hermetic fixation of preservatives' ends; - a proximal preservative. In addition, the control block of the endoscopic tube could be made in the desktop manner, and the cock, which feeds the working pressure into the everted part of invaginator, could be placed in the pedal.

Pneumo-hydro-manual system for introduction and extraction of biopsy forceps comprises of pressure and vacuum sources, which are connected through a cock to the cavity of a biopsy channel, the entrance to which is sealed with a seal of biopsy forceps, and the distal end of said forceps has a piston of the biopsy channel.

The biopsy forceps with a pneumo-hydraulic intensifier of traction line comprise a flexible hermetic tube, which is connected with sources of pressure and vacuum, and the distal end of the tube and the traction line finishes with a cylinder and a piston.

BRIEF DESCRIPTION OF THE DRAWINGS.

The graphic materials clarify the essence of invention, where on the FIG.1 is represented the endoscope with disposable cartridge for invagination, wherein: a – a handle-shaped control block; b – distal part of the endoscope with mounted cartridge; c - longitudinal section of the cartridge; d, e, f - enlarged fragments of FIG.1c. On FIG. 2 is represented the system of extraction-intraction of traction lines with pneumo-hydro-manual drive, when the distal end of the endoscope is in direct position, wherein: a - a state of system elements comprised in the control block; b - enlarged fragment of FIG. 2a; c - distal part of the endoscope with "bared" system elements (vertical arrows show the top-bottom of the endoscopic tube); d – enlarged fragment of FIG. 2c. On FIG. 3 is represented the system of extraction-intraction of traction lines when the end of the endoscope is bent downwards, wherein: a - a state of elements comprised in the control block; b – enlarged fragment of FIG. 3a; c - distal part of the endoscopic tube with "bared" elements (horizontal arrows show the driving direction of the traction lines); d, e - enlarged fragments of FIG. 3c. On FIG. 4 are represented: a - a design of new endoscope; b - a crosspiece with a

lever bending the distal end of endoscope in any direction; c – a construction of a mechanism for introduction of the endoscopic tube; d – a system of extraction and intraction of biopsy forceps.

DESCRIPTION OF THE PREFERRED EMBODIMENTS.

Specification of numerical markings of FIGs. 1-4 is given at the end of the description. A novel endoscope includes an endoscopic tube 3 with a control block 2 and a communication branch. An air-duct 15 and a cock 17 positioned on the control block 2 or in a pedal, connect a source of working pressure with an opening 21 into the cavity of a seal 13, which cavity communicates with a cavity 14 of a shell 22. The distal part of the shell 22 is commensurable by length and diameter to the uneverted part of an invaginator 23, and its proximal part – to a compressed spring 10. The everted end 12 of the invaginator 23 is fastened on the shell 22 by a ring 16. The invaginator 23 has narrowings and widenings 24, as well as a gap 25 with a distal preservative 26. Ends of the distal 26 and a proximal 27 preservatives as well as corresponding places of the tube 3 have areas 28 for interconnection and hermetization. A seal 29 on the end 7 of the invaginator 23 separates the cavity 14 from the cavity 25, which communicates with the intestinal cavity. A distancer 30 prevents deformation of the seal 29 by the spring 10. Ends of compressed spring 10 are rested on the distancer 30 and a stop 11 at the end 28 of the preservative 26. The stop 11, in its turn, is positioned on a projection 31 of the shell 22. The distal end of the preservative 26 finishes by a tip 6 with channels 32 for washing of a protective glass 33 and inflating of intestines, and with an element for fixation to the endoscopic tube 3. On the border between narrow and wide parts of the shell 22, there is an area with an intermediate diameter, wherein is pressed an elastic ring 34 for fixation of the compressed spring 10. A channel 35 in an anal dilator 19 is used for decompression of intestines during intubation. In the tube 3, in addition to afore-enumerated, there are elastic tubes 36, 37 comprising springs 38, 39 and traction lines 40, 41. The tubes 36, 37 are connected to the springs 38, 39 with a thread 42. Near to a mechanism 43 for bending of the distal end of the tube 3, the ends of the tubes 36, 37 are closed with plugs 44, which plugs also connect the springs 38, 39 with the traction lines 40, 41. Proximal ends of tubes 36, 37 are connected with sources 45 of excess pressure and vacuum. Proximal ends of the traction lines 40, 41 are connected with their manual extractors-intractors 46, and said extractors-intractors - with an element 47, which ensures synchronous feeding of vacuum into the cavity of the extracted traction line 40 and of pressure into the cavity of the introduced traction line 41. The endoscopic tube 3 has internal pleats 48 of its external cover, an air-duct 49 with two openings 50, which serve for vacuum fixation of the preservatives 26, 27 to the tube 3; additionally the tube 3 has a removable sleeve gasket 51. The control block 2 has a cock 52 of the air-duct 49. The seal 13 is hermetically connected to a mechanism 53 for introduction of the endoscopic tube 3. The mechanism 53 for introduction of the tube 3 is operated by a pedal 54 and a lever 55 controls the bending of tube's end. A cylinder 56, two pistons 57, distancers 58 and an elastic tube 59 limit a cavity 60, which is connected with a source of pressure by means of a cock in the pedal 54. A cavity 61 comprises a return spring 62 and is connected with a source of vacuum by means of a cock in the pedal 54. A seal 64 and a nut 65 are mounted on biopsy forceps 63, while at the distal end of said forceps a piston 66 is positioned. Seat for the seal 64 and the nut 65 is located at an entry 67 to the biopsy channel, which entry as well as a cock 68 are positioned on control block 2. A sylphone 69, which serves as a source of pressure and vacuum in a pneumatic intensifier of traction line of biopsy forceps, could be combined with a handle of biopsy forceps 63.

Marks made on the preservative 27 and the tube 3 serve for their correct connection. After that the mechanism 53 is mounted on the tube 3 and the cartridge for invagination is fixed. Pressing on the cock 52 will ensure the vacuum fixation of the preservatives 26, 27 to the tube 3. After introduction of the seal 13 into the cylinder 56, endoscope's preparation for work is completed.

After the patient has been placed on an endoscopic table, the cartridge is oiled and introduced into the rectum and its ampoule is examined as if with a rigid rectoscope. The pressure in the cavity 14 is increased by pressing the cock 17 thus freeing the distancer 30 from coupling with the fixator 34 and the shell 22. Thus, the spring 10 is released and it is possible to proceed with invagination of the tube 3. Eversion of the invaginator 23 and introduction of the tube 3 into the colon occurs under working pressure in the cavity 14 at moments when the pedal 54 is pressed. In the course of the endoscopy the intestines are to be inflated. Gas into intestines is constantly supplied through a gas/liquid channel in the tube 3 and further through the channel 32 of the tip 6 thus preventing ingress of intestinal contents under the protective glass 33. Gas evacuation from intestines occurs through the channel 35 of the anal dilator 19.

Bending of the mechanism 43 is realized by means of the sources 45 of excessive pressure and vacuum, by manual extractors-intractors 46 of traction lines 40, 41 and by means of elements 47 which ensure feeding of vacuum into the cavity of the tube 36 which comprises the extracted traction line 40, and feeding of excessive pressure in the cavity of the tube 37 which comprises the introduced traction line 41. Under the action of vacuum the elastic tube 36 and the spring 38 are shortened. Considering, that their distal end is connected with the traction line 40, this shortening relieves manual extraction of this traction line. Under the action of pressure in the tube 37 this tube and the spring 39 elongates towards the executing mechanism 43 thus relieving manual intraction of the traction line 41. The thread 42 twisted on tubes 36, 37, combines these tubes with the springs 38, 39. Thus, vacuum and pressure, which shorten and elongate the tubes 36, 37 and the springs 38, 39, ensure application of forces to distal ends of traction lines 40 and 41; manual extraction and intraction of the traction lines 40, 41, create synchronous efforts on proximal ends of traction lines. The mechanism 43 of the tube 3 is bent downwards by the above-mentioned method. When the mechanism 43 is bent upwards, all above enumerated elements are moved in opposite directions; the second pair of traction lines, which work similarly, implement bending of the mechanism 43 to the left and to the right. In intermediate positions the mechanism 43 is bent by interchangeable use of both pairs of traction lines. The element 47 made in the shape of a crosspiece with the lever 55, ensures simultaneous bending of the mechanism 43 in any direction.

As now in the course of colonoscopy the tube 3 repeats all natural flexures of the colon, tube's extubation must not be accelerated. The anal dilator 19, through which extubation is to be conducted, reduces to minimum unpleasant sensations caused by this process.

The most practically important embodiment of the invention is a colonoscope with the endoscopic tube 3 without biopsy channel. The disposable cartridge ensures an available to all and atraumatic transportation of the tube 3 in the colon, preservatives 26, 27 protect the patient from infections seated in the endoscopic tube 3, and the tube 3 in its turn - from getting contagious during endoscopy. Ergonomics of

operating with such colonoscope also makes it available to any physician: during endoscopy a physician in sedentary position watches the screen, presses the pedal cock 17 with one foot and the pedal 54 with another, with the right hand controls the lever 55, and in case of necessity washes the protective glass 33 by pressing on the cock with the left hand. Such colonoscope is necessary firstly for family doctors, gastroenterologists and surgeons for the regular colon cancer screening. Having selected the "suspicious" patients, out-patient physicians will direct them to an in-patient clinic for biopsy taking and other thorough examinations.

For biopsy taking is used a cartridge with the tip 6, without the glass 33. Having exhausted the possibility of manual insertion of the forceps 63, it is necessary by means of the seal 64 and the nut 65 to seal hermetically the entry 67 into the biopsy channel and connect it by means of the cock 68 to the source of pressure. Further insertion of the forceps 63 is performed by their manual intraction and due to liquid or gas pressure on the piston 66, while forceps' extraction is performed by switching the cock 68 in the "vacuum" position and by manual extraction of the forceps 63. Due to location of the pressure and vacuum source 69 of the traction line intensifier in the handle of said forceps, bioptate taking is implemented as previously - approach of rings ensures movement of the traction line inwards, while rings' detachment - extraction of the traction line.

Specification of graphic materials' markings on fig. 1-4 is as follows:

2 – the control block with the communication branch-tube;
3 – the endoscopic tube;
6 – the tip of the endoscopic tube 3;
7 – the uneverted end of the invaginator 23;
10 – the compressed spring;
11 – the stop for the spring 10;
12 – the everted end of the invaginator 23;
13 – the proximal seal of the tube 3;
14 – the cavity of the everted part 4 of the invaginator 23;
15 – the air-duct for feeding of working pressure into the cavity 14;
16 – the ring, fixing the end 12 of the invaginator 23;
17– the cock of the air-duct 15;
19 – the anal dilator;
21 – the opening of the air-duct 15 on the tube 3;
22 – the shell of cartridge for invagination;
23 – the invaginator formed into a compact flexible cylinder;
24 – the narrowings and widenings of the cylinder of the invaginator 23;
25 – the gap (cavity) between the cylinder of invaginator 23 and the preservative 26;
26 – the distal preservative of the tube 3;
27 – the proximal preservative of the tube 3;
28 – the areas on the tube 3 and on the ends of preservatives 26, 27 for their hermetic connection;
29 – the distal seal between the tube 3 and the end 7 of the invaginator 23;
30 – the distancer between the spring 10 and the invaginator 23, which distancer comprises the seal 29;

31 – the projection on the shell 22 for the stop 11;

32 – the channel in the tip 6;

33 – the protective glass of the tip 6;

34 – the elastic ring, fixing the spring 10 in compressed state;

35 – the channel in the anal dilator 19;

36 – the lower elastic tube of extractor-intractor of traction lines;

37 – the upper elastic tube of extractor-intractor of traction lines;

38 – the lower spring of extractor-intractor of traction lines;

39 – the upper spring of extractor-intractor of traction lines;

40 – the lower traction line of extractor-intractor of traction lines;

41 – the upper traction line of extractor-intractor of traction lines;

42 – the thread fixing the elastic tubes 36, 37 to the springs 38, 39;

43 – the mechanism for bending of the distal end of the tube 3;

44 – the plug, which closes the tubes 36, 37 and connects the springs 38, 39 with the traction lines 40, 41;

45 – the sources of pressure and vacuum;

46 – the manual extractors-intractors of the traction lines 40, 41;

47 – the element for extraction-intraction of one or two pairs of the traction lines;

48 – the pleats of external cover of the tube 3;

49 – the air-duct into cavity of the preservatives 26, 27;

50 – the distal and proximal openings of the air-duct 49 on the tube 3;

51 – the sleeve gasket;

52 – the cock of the air-duct 49 on the control block 2;

53 – the mechanism for insertion of the endoscopic tube 3;

54 – the pedal for switching on the mechanism 53;

55 – the lever of the element 47, made in a shape of a crosspiece;

56 – the cylinder of the mechanism 53;

57 – the pistons of the cylinder 56;

58 – the distancers between the pistons 57;

59 – the elastic tube, attached to the pistons 57;

60 – the hermetic cavity, enclosed by the elastic tube 59 and the pistons 57;

61 – the hermetic cavity, enclosed by the seal 13 and the distal piston 57;

62 – the spring, returning the pistons 57 to home position;

63 – the biopsy forceps;

64 – the seal of the entry 67 into a biopsy channel;

65 – the nut, fixing the seal 64;

66 – the piston of the biopsy forceps;

67 – the entry into a biopsy channel;

68 – the cock, which feeds pressure or vacuum into a biopsy channel;

69 – the source of pressure and vacuum connected with the cavity of biopsy forceps 63;

70 – the cutters of the biopsy forceps 63;

71 – the distal intensifier (drive) of the traction line of the cutters 70.